10. 510(k) SUMMARY

Date of Summary:
July 6, 2001

Product Name:
QUIK-CHECK™ Ovulation Predictor Test

Sponsor's Name:
ACON Laboratories, Inc.
4108 Sorrento Valley Blvd.
San Diego, CA 92121
Establishment Number : 2531491

Manufactured by:
ACON Biotech (Hangzhou) Co. Ltd.
118 Tianmushan Rd.
Gudang Industrial Park
Hangzhou, P.R. China 310023
Owner/Operator Number: 9033096

Correspondent in the U.S.:
MDC ASSOCIATES
Fran White
Regulatory Consultant
163 Cabot Street
Beverly, MA 01915

Substantially Equivalent Device:
Product: ClearPlan Easy® Ovulation Test
Manufactured by: Unipath
K Number: K981207

PRODUCT DESCRIPTION:

The QUIK-CHECK™ Ovulation Predictor Test is a midstream test used for the qualitative measurement of Luteinizing Hormone (LH) and the detection of the LH surge in a woman's urine as an aid in reliably predicting ovulation. The ovulation predictor test is intended for use outside the body (*in vitro* diagnostic use) by women at home. The QUIK-CHECK™ Ovulation Predictor Test is an over-the-counter (OTC) device that will be sold under the QUIK-CHECK™ brand and various private labels.

INTENDED USE:

QUIK-CHECK™ Ovulation Predictor Test is a qualitative, one-step, midstream assay for the detection of human Luteinizing Hormone (LH) in urine as an aid in conception by reliably predicting ovulation. The QUIK-CHECK™ Ovulation Predictor Test is intended for use by the lay consumer.

SUMMARY OF TECHNOLOGY:

The QUIK-CHECK™ Ovulation Predictor Test employs a unique combination of monoclonal antibody-dye particle conjugates and polyclonal-solid phase antibodies to selectively identify human Luteinizing Hormone (LH) in urine. As the urine flows through the absorbent portion of the device, the antibody-dye particle conjugate binds to the LH, forming an antibody-antigen complex. This complex binds to the anti-LH antibody in the test zone and produces a pink-rose color band. The color intensity of this band is equal to or greater than that of the control band when the LH concentration is greater than 40 mIU/mL. In urine with LH concentrations of less than 40 mIU/mL, the band in the test zone will appear lighter than the control band. In the absence of LH in urine, no test band will show up in the test zone. The test has also incorporated a control system where a pink-colored band will always appear in the control zone, demonstrating that the test is functioning correctly.

PERFORMANCE DATA:

A clinical trial was done to compare the performance of the QUIK-CHECK™ Ovulation Predictor Test to a substantially equivalent product (ClearPlan Easy®) manufactured by Unipath. Data clearly demonstrate that the performance of the QUIK-CHECK™ Ovulation Predictor Test is substantially equivalent to the ClearPlan Easy® Test.

QUIK-CHECK™ Ovulation Predictor Test vs. ClearPlan Easy® Ovulation Test:
100 females tested the QUIK-CHECK™ Ovulation Predictor Test to determine their respective LH surges over a period of ten consecutive days for one menstrual cycle. Each volunteer conducted the testing at home according to the package insert instructions. The urine samples were refrigerated and provided to the study coordinator. The study coordinator tested each sample using the QUIK CHECK™ and the ClearPlan Easy® Tests. The data obtained was recorded as Negative (no surge) or Positive (surge).

Summary of Results:

Tests (tester)	Accuracy
QUIK-CHECK™ (Trained Lab Technician) vs. ClearPlan Easy® (Trained Lab Technician)	>99% (99% - 100%*)
QUIK-CHECK™ (Consumer) vs. ClearPlan Easy® (Consumer)	95% (94% - 96%*)
QUIK-CHECK™ (Trained Laboratory Technician) vs. QUIK-CHECK™ (Consumer)	95% (94% - 96%*)

* 95% confidence Intervals

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 1 8 2001

ACON Laboratories, Inc.
c/o Ms. Fran White
Regulatory Consultant
163 Cabot Street
Beverly, MA 01915

Re: K012252
Trade/Device Name: QUIK-CHECK™ Ovulation Predictor Test
Regulation Number: 21 CFR 862.1485
Regulatory Class: I, reserved
Product Code: CEP
Dated: July 6, 2001
Received: July 18, 2001

Dear Ms. White:

This letter replaces and corrects letter dated August 24, 2001. The device name was incorrect. It was spelled Quick-Check. It should be spelled Quik-Check.

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: _____
Device Name: QUIK-CHECK™ Ovulation Predictor Test

Indication for Use:

The QUIK-CHECK™ Ovulation Predictor Test is a qualitative, one-step, midstream assay for the detection of human Luteinizing Hormone (LH) in urine as an aid in conception by reliably predicting ovulation. The QUIK-CHECK™ Ovulation Predictor Test is intended for use by the lay consumer.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ **OR** **Over The Counter Use** _____
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**

Kesia Alexander for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012252